

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 532571
Issued To: **Nox Medical**
Katrínartúni 2
Reykjavík
IS-105
Iceland

In respect of:

The design and manufacture of sleep diagnostic devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2008-08-28**

Date: **2019-02-14**

Expiry Date: **2023-08-27**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Jiangyin Sinbon
No 288 Chengjiang Middle Road
Economic and Development Zone
Jiangyin City
Jiangsu Province
214434
P.R. China

Manufacture

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Certificate History

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 Reykjavík
 IS-105
 Iceland**

Date	Reference Number	Action
28 August 2008	7146275	First Issue
05 May 2010	7520233	Certificate reissue due to change of address from: Nox Medical, Impra Keldnaholti, Reykjavik, IS-112, Iceland to: Nox Medical, Vatnagordum 18, Reykjavik, IS-104, Iceland
23 November 2011	7718422	Certificate reissue due to change of scope to include design. Product Standard changed from 93/42/EEC, Annex V, Section 3.2 to 93/42/EEC, Annex II, Section 3.2.
05 February 2013	7946029	Certificate reissue due to change of company address from 'Vatnagordum 18, IS-104 Reykjavik' to 'Katrínartúni 2, IS-105 Reykjavík'
26 July 2013	7982981	Certificate Renewal
13 July 2018	8892229	Certificate Renewal Correction to sub-contractor address Jiangyin SINBON Electronics Co., Ltd
Current	7780268	Traceable to NB 0086.

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Page 1 of 1

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